

## Cluster randomised controlled trial

## Hand hygiene and face mask use within 36 hours of index patient symptom onset reduces flu transmission to household contacts

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This study is one of four published clinical trials of the use of face masks in community settings.<sup>1–3</sup> Cowling and colleagues used a prospective cluster randomised controlled trial (RCT) design, identifying well families of index patients with flu confirmed by rapid testing from outpatient clinics in Hong Kong. Households were randomised to control (n=279), hand hygiene (n=257) or hand hygiene plus face masks (n=258). The masks used were medical/surgical ones. Outcomes measured for a follow-up period of 6 days were the development of clinical flu-like illness as measured by two different case definitions and confirmation of flu by real-time PCR (RT-PCR). By intention-to-treat analysis there were no significant differences between the arms. However, in a subgroup analysis of outcomes within 36 hours, there was as significant reduction in RT-PCR-confirmed flu in the face mask plus hand hygiene group, and for one of the clinical case definitions for both intervention groups. There was no significant difference between the two intervention arms. The authors conclude that hand hygiene and face masks reduce the risk of flu if applied within 36 hours of exposure.

This type of study is challenging to conduct because of the dynamic nature of flu transmission, the potential herd effects of interventions to control infectious diseases and the intensive nature of the required follow-up. The design is appropriate, and more efficient than the previous design used by the same authors.<sup>2</sup> The

study outcomes selected were appropriate. Defining flu cases on the basis of RT-PCR alone (without serology) is more robust, as serology is far less definitive and is subject to false positives as a result of vaccination or cross-reaction. Using a clinical case definition in addition to laboratory confirmation is valuable as it may capture cases missed by PCR and other respiratory virus infections.

The study reiterates the value of hand hygiene in controlling flu in the household setting. Its limitation is that it is unable to separate the efficacy of face masks and hand hygiene: as there was no significant difference between the intervention arms, all observed efficacy could be due to hand hygiene alone, which appears to be the dominant protective effect. There may be value in using face masks, but the study was probably underpowered, and further studies are required to compare the two interventions head to head in an RCT design. The results are similar to those of a study among college students in the USA, which also showed a possible impact of hand hygiene and masks but could not differentiate the independent effect of masks.<sup>2</sup>

**Competing interests** CRM has conducted investigator-driven clinical research on face masks. She has received support in the form of provision of masks from 3M for some of her studies. She has also received grants and support for investigator-driven research from GlaxoSmithKline,

CSL Biotherapies and Wyeth. She is working on face mask research with GlaxoSmithKline.

### References

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